MONITORING TO VERIFY CONFINEMENT

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Public policy regarding the unintended occurrence of transgenic elements in the food supply necessitates that regulated transgenes be confined. Within this context, transgene confinement stands as a rights-based criterion[1] for genetically engineered crops separate from the risks (human, environmental, or economic consequence) that the transgenic elements (or more specifically, their expressed products) may pose. USDA-APHIS has established permitting conditions for field testing of genetically engineered crops that produce pharmaceutical or industrial compounds in order to limit unintended occurrence of regulated transgenic elements consistent with public policy expectations.[2,3]

Monitoring is used to verify that the processes for achieving confinement meet expectations. Monitoring for gene flow may be physically based (focused on detection of gene flow), process based (focused on the conditions of confinement), or model based (focused on environmental factors governing gene flow). In selecting a monitoring approach consideration needs to be given to seeking transient occurrence (as in episodic occurrence in food or feed) versus accumulation (occurrence in the breeder's seed bank).

The monitoring threshold for concern and confinement parameters will greatly influence the feasibility of physically-based monitoring. For instance, confinement to assure that out-crossing from corn is restricted to <1% at distances within ca 200 m of a source may be reasonably predicted and monitored, whereas, physical verification that out-crossing is near zero at 1610-m cannot be directly achieved on the basis of existing data, predictive tools, or analytical methodology. Sentinel monitoring using catch plots for gauging out-crossing has been used to describe attenuation of out-crossing with distance off-source and extrapolate near source measurements to distant receptors.[4] The veracity of this approach is of yet not clearly established due to the aforementioned limitations regarding level of detection and modeling for distant transport.[5] Improved monitoring and modeling approaches are emerging that allow for real time monitoring and analysis of environmental conditions leading to fugitive pollen escape, and these approaches can be used to identify, isolate, and remediate unintended escapes if confinement is breached.[6] Until validated monitoring and modeling approaches for the physical flow of genes to great distances are available, monitoring of the management processes intended to achieve confinement goals stands as the most effective means to assure confinement of genetically engineered crops.

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[1] See for example, *zero risk criterion* for public policy as described by Morgan and Henrion (1990) *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*, Cambridge University Press.

[2] United States Department of Agriculture [USDA] (2003) Field testing of plants to produce pharmaceutical and industrial compounds. *Federal Register* 68(46)11337-11340.

[3] United States Department of Agriculture [USDA] (2003) Introductions of plants genetically engineered to produce industrial compounds. *Federal Register* 68(151)46434-46436.

[4] Eppard (2002) Confinement Strategies for Plant-Made Pharmaceuticals (PMP). pewagbiotech.org/events/0717/presentations/Eppard.ppt accessed electronically 13 Aug 04.

[5] See for example, the review and analysis of Aylor et. al (2003) An aerobiological framework for assessing cross-pollination in maize, *Agric. Forest Meteorol.* 119:111-129.

[6] Hayes (2004) Economic Cost associated with pollen flow from transgenic crops, Risk Analysis Symposium: Corn Produced Pharmaceuticals and Industrials, Ames, Iowa, 22 Apr 2004. http://www.bigmap.iastate.edu accessed electronically 23 Aug 2004.